

Serial No. 09/971,799
Attorney Docket No. PG4113US2

Amendments to the Claims:

Please amend the claims as follows:

1. (Original) A drug product comprising:
a drug formulation comprising a mixture of at least a drug and a hydrofluoroalkane propellant;
a pressurized container filled with said drug formulation; and,
a pouch constructed from materials comprising one or more metallic foil layers and one or more moisture absorbing materials.
2. (Original) The drug product of claim 1 wherein the drug is selected from the group consisting of (-)-4-amino-3,5-dichloro-alpha-{{6-{2-(2-pyridinyl)ethoxy}hexyl}-amino}methyl}benzenemethanol, flunisolide, tiredane, triamcinalone, isoprenaline, metaproterenol, perbuterol, peproterol, rimiterol, ephedrine, fenoterol, formoterol, atropine, oxitropium, acetonide, phenylephrine, phenylpropanolamine, terbutaline, isoetharine, tulobuterol, orciprenaline, salts, esters and solvates thereof, and combinations thereof.
3. (Original) The drug product of claim 1 wherein the drug is a member selected from the group consisting of fluticasone, beclomethasone, salmeterol, albuterol, budesonide, salbutamol, ipratropium, salts, esters and solvates thereof, and combinations thereof.
4. (Original) The drug product of claim 1 wherein the drug is fluticasone propionate.
5. (Original) The drug product of claim 1 wherein the drug is beclomethasone dipropionate.
6. (Original) The drug product of claim 1 wherein the drug is salmeterol xinafoate.
7. (Original) The drug product of claim 1 wherein the drug is a salt, solvate or ester a combination of salmeterol and ipratropium.
8. (Original) The drug product of claim 1 wherein the drug is salmeterol xinafoate and ipratropium bromide.

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9. (Original) The drug product of claim 1 wherein the drug is a salt, solvate or ester of a combination of salmeterol and fluticasone.

10. (Original) The drug product of claim 9 wherein the drug is a combination of salmeterol xinafoate and fluticasone propionate.

11. (Original) The drug product of claim 1 wherein the drug is salbutamol sulphate.

12. (Original) The drug product of claim 1 wherein the hydrofluoroalkane propellant is a member selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoro-n-propane and mixtures thereof.

13. (Original) The drug product of claim 1 wherein the hydrofluoroalkane propellant is 1,1,1,2-tetrafluoroethane.

14. (Original) The drug product of claim 1 further including a metering valve engaged to the pressurized container.

15. (Original) The drug product of claim 14 further including an actuator adapted to engage the metering valve and the pressurized container.

16. (Original) The drug product of claim 15 wherein the moisture absorbing material is a desiccant.

17. (Original) The drug product of claim 16 wherein the actuator, metering valve and pressurized container and metering valve are contained within the pouch.

18. (Original) The drug product of claim 16 wherein the desiccant is selected from the group consisting of nylon, silica gel, alumina, bauxite, anhydrous, calcium sulfate, water-absorbing clay, activated bentonite clay, a molecular sieve zeolite and combinations thereof.

19. (Original) The drug product of claim 1 wherein the drug formulation consists essentially of a drug and a hydrofluoroalkane propellant.

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20. (Original) The drug product of claim 15 wherein desiccant is in the form of a coating, lining, film or mesh.

21. (Original) The drug product of claim 20 wherein the desiccant is a nylon.

22. (Original) The drug product of claim 1 wherein the metallic foil layer is aluminum.

23. (Original) The drug product of claim 22 wherein the aluminum foil layer has a thickness in the range of 9-25 μm .

24. (Original) The drug product of claim 23 wherein the aluminum foil layer has a thickness of about 12.7 μm .

25. (Canceled)

25 26. (Original) The drug product of claim 1 wherein the pouch is vacuum sealed.

26 27. (Original) The drug product of claim 1 wherein the pouch is purged with nitrogen gas.

27 28. (Original) The drug product of claim 1 further comprising a second desiccant loosely contained within the pouch.

28 29. (Original) The drug product of claim 1 further comprising a second desiccant contained within the pressurized container.

29 30. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 1-100 μ .

30 31. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 3-70 μ .

31 32. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 5-50 μ .

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³²33. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness in the range of 6-20 μ .

³³34. (Original) The drug product of claim 1 wherein the metallic foil layer has a thickness of about 9 μ .

³⁴35. (Original) The drug product of claim 1 wherein the pouch includes one or more protective layers.

³⁵36. (Original) The drug product of claim ³⁴35 wherein the protective layer has a thickness in the range of 1-40 μ .

³⁶37. (Original) The drug product of claim ³⁴35 wherein the protective layer has a thickness in the range of 4-30 μ .

³⁷38. (Original) The drug product of claim ³⁴35 wherein the protective layer has a thickness in the range of 10-23 μ .

³⁸39. (Original) The drug product of claim ³⁴35 wherein the protective layer has a thickness of about 12 μ .

³⁹40. (Original) The drug product of claim 1 wherein the metallic foil layer includes a metal collected from the group consisting of aluminum, tin, iron, zinc and magnesium.

⁴⁰41. (Original) The drug product of claim ³⁹40 wherein the metallic foil layer includes aluminum.

⁴¹42. (Original) The drug product of claim ³⁹40 wherein the metallic foil layer of the pouch is constructed by the act of vacuum deposition.

⁴²43. (Original) The drug product of claim ³⁹40 wherein the metallic foil layer of the pouch is constructed by the act of sputtering.

⁴³44. (Original) The drug product of claim 1 wherein the drug formulation further includes an excipient.

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⁴⁴45. (Original) The drug product of claim ⁴³44 comprising 0.01-5% w/w of the excipient.

⁴⁵46. (Original) The drug product of claim ⁴⁷44 comprising 0.05-5% w/w of the excipient.

⁴⁶47. (Original) The drug product of claim ⁴³44 comprising 0.1-5% w/w of the excipient.

⁴⁷48. (Original) The drug product of claim ⁴³44 comprising 0.1-1% w/w of the excipient.

⁴⁸49. (Original) The drug product of claim ⁴³44 wherein the excipient is a member selected from the group consisting of one or more surfactants, preservatives, flavorings, antioxidants, anti-aggregating agents, co-solvents, and combinations thereof.

⁴⁹50. (Original) The drug product of claim ⁴⁸49 wherein the co-solvent is ethanol or diethyl ether.

⁵⁰51. (Original) The drug product of claim ⁴⁸49 wherein the co-solvent is C₂₋₆ aliphatic alcohols or C₂₋₆ aliphatic polyols.

⁵¹52. (Original) The drug product of claim ⁴⁸49 wherein the co-solvent is glycerol, isopropanol or propylene glycol.

⁵²53. (Original) The drug product of claim ³⁴35 wherein the pouch further includes one or more heat seal layers.

⁵³54. (Original) The drug product of claim ³⁴35 wherein the pouch further includes one or more adhesive layers.

⁵⁴55. (Original) The drug product of claim ³⁴35 wherein the protective layer includes one or more desiccants impregnated therein.

Claim 56 (Canceled).

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⁵⁵57. (Original) The drug product of claim ⁵⁷54 wherein one or more adhesive layers include one or more desiccants.

⁵⁶58. (Original) The drug product of claim ⁵⁴35 wherein the protective layer includes a polyester.

⁵¹59. (Original) The drug product of claim ⁵⁶58 wherein the protective layer has a thickness of about 12 μ .

⁵⁸60. (Original) The drug product of claim ²²22 wherein the metallic foil layer has a thickness of 9 μ .

⁵⁹61. (Original) The drug product of claim ⁵²53 wherein the heat seal layer includes a member selected from the group consisting of an ionomer, a polyolefin, a cyclopolyolefin copolymer and combinations thereof.

⁶⁰62. (Original) The drug product of claim ⁵⁹61 wherein the heat seal layer includes an ionomer selected from the group consisting of crosslinked ethylene-methacrylic acid and ethylene acrylic acid copolymer, and wherein the heat seal layer has a thickness of 50 μ .

⁶¹63. (Original) The drug product of claim ⁵²53 wherein the heat seal layer has a thickness in the range of 1-100 μ .

⁶²64. (Original) The drug product of claim ⁵²53 wherein the heat seal layer has a thickness in the range of 5-70 μ .

⁶³65. (Original) The drug product of claim ⁵²53 wherein the heat seal layer has a thickness in the range of 10-60 μ .

⁶⁴66. (Original) The drug product of claim ⁵²53 wherein the heat seal layer has a thickness in the range of 20-55 μ .

⁶⁵67. (Original) The drug product of claim ⁵²53 wherein the heat seal layer has a thickness of 50 μ .

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⁶⁶68. (Original) The drug product of claim ⁵²53 wherein the heat seal layer is adhesively laminated to the metallic foil layer by an adhesive layer.

⁶⁷69. (Original) The drug product of claim ³⁴35 wherein the protective layer is adhesively laminated to the metallic foil layer.

⁶⁸70. (Original) The drug product of claim ²⁶20 wherein desiccant is adhesively laminated to one or more of the protective layer, the metallic foil layer or the heat seal layer.

⁶⁹71. (Original) A drug product comprising:
a drug formulation comprising a mixture of at least a drug and a hydrofluoroalkane propellant;
a pressurized means for containing said drug formulation; and,
a means for pouching the pressurized means constructed from materials comprising one or more metallic foil layers and one or more moisture absorbing materials.

Claims 72-80 (Canceled).

⁷⁰81. (Previously Presented) The drug product of claim ⁶⁹71 wherein the drug is albuterol sulfate.

⁷¹82. (Previously Presented) The drug product of claim ⁶⁹71 wherein the drug is fluticasone propionate.

⁷²83. (Previously Presented) The drug product of claim ⁶⁹71 wherein the drug is salmeterol xinafoate.

⁷³84. (Previously Presented) The drug product of claim ⁶⁹71 wherein the drug is a combination of fluticasone propionate and salmeterol xinafoate.

⁷⁴85. (Previously Presented) The drug product of claim ⁶⁹71 wherein the drug is beclomethasone dipropionate.

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75 86. (Previously Presented) The drug product of claim 71 wherein the drug is a combination of a salt, ester or solvate thereof of salmeterol and ipratropium.

76 87. (Original) The drug product of claim 86 wherein the drug is a combination of a combination of salmeterol xinafoate and ipratropium bromide.

77 88. (Previously Presented) The drug product of claim 71 wherein the drug is selected from the group consisting of (-)-4-amino-3,5-dichloro-alpha-{{6-{2-(2-pyridinyl)ethoxy}hexyl}-amino}methyl}benzenemethanol, flunisolide, tiredane, triamcinalone, isoprenaline, metaproterenol, perbuterol, peproterol, rimiterol, ephedrine, fenoterol, formoterol, atropine, oxitropium, acetonide, phenylephrine, phenylpropanolamine, terbutaline, isoetharine, tulobuterol, orciprenaline, salts, esters and solvates thereof, and combinations thereof.

78 89. (Previously Presented) The drug product of claim 71 wherein the drug is a member selected from the group consisting of fluticasone, beclomethasone, salmeterol, albuterol, budesonide, salbutamol, ipratropium, salts, esters and solvates thereof, and combinations thereof.

79 90. (Previously Presented) The drug product of claim 71 further including a metering valve engaged to the pressurized means.

80 91. (Previously Presented) The drug product of claim 90 further including an actuator adapted to engage the metering valve and the pressurized means.

81 92. (Previously Presented) The drug product of claim 91 wherein the actuator, metering valve and pressurized means and metering valve are contained within the means for pouching the pressurized means.

82 93. (Previously Presented) The drug product of claim 71 wherein the drug formulation consists essentially of a drug and a hydrofluoroalkane propellant.

83 94. (Previously Presented) The drug product of claim 71 wherein the means for pouching the pressurized means is vacuum sealed.

84 95. (Previously Presented) The drug product of claim 94 wherein the means for pouching the pressurized means is purged with nitrogen gas.

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96, (Previously Presented) The drug product of claim ⁸⁷71 wherein the drug formulation further includes an excipient.

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97. (Original) The drug product of claim ⁸⁵96 comprising 0.01-5% w/w of the excipient.

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98. (Original) The drug product of claim ⁸⁵96 comprising 0.05-5% w/w of the excipient.

⁸⁸
99. (Original) The drug product of claim ⁸⁵96 comprising 0.1-5% w/w of the excipient.

⁸⁹
100. (Original) The drug product of claim ⁸⁵96 comprising 0.1-1% w/w of the excipient.

⁹⁰
101. (Original) The drug product of claim ⁸⁵96 wherein the excipient is a member selected from the group consisting of one or more surfactants, preservatives, flavorings, antioxidants, anti-aggregating agents, co-solvents, and combinations thereof.

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102. (Original) The drug product of claim ⁹⁰101 wherein the co-solvent is ethanol or diethyl ether.

⁹²
103. (Original) The drug product of claim ⁹⁰101 wherein the co-solvent is C₂₋₆ aliphatic alcohols or C₂₋₆ aliphatic polyols.

⁹³
104. (Original) The drug product of claim ⁹⁰101 wherein the co-solvent is glycerol, isopropanol or propylene glycol.

105-124. (Canceled)

⁹⁴ 125. (Original) A drug product comprising:
a means for dispensing metered amounts of fluid material from a means for reserving the fluid material;
a drug formulation located within said dispensing means comprising a pharmaceutically acceptable medicament and propellant; and
a flexible packaging means for overwrapping and sealing said dispensing means,

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10 wherein said flexible packaging means is impermeable to water vapor and permeable to said propellant,
and wherein said flexible packaging means substantially prevents ingress of water vapor and particulate matter and permits egression of said propellant.
